or nasal passage.

REMARKS

Claim 26 had previously been amended and submitted to the U.S. Patent and Trademark Office in a preliminary amendment.

Applicant takes issue with the Office Action of April 14, 1999. Specifically, the Office Action states:

> "Claims 26-51 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The recitation in the claims of pH range of the enzyme ranging from 4.0 to 8.0 (p7) is a feature that is critical or essential to the practice of the invention, but not included in the claim(s). Hence, the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 U.S. P.Q. 356 (CCPA 1976). Note that the above-mentioned limitation is <u>not</u> a preferred embodiment of the present invention but a critical limitation. Claims are read in light of the specification, and the claims in this case are not commensurate in scope with the specification in the absence of this limitation. In other words, the present claims <u>do not</u> "reasonably correlate" with the scope of the specification. Therefore, "undue experimentation" would be required by one of ordinary skill in the art at the time of this invention."

In fact, there has been a misreading of the application, as the pH selection is a preferred embodiment of the invention. The specification reads as follows:

> "Prior to, or at the time the enzyme is put in a carrier system, the enzyme **may be** (emphasis added) in a phosphate buffer environment for maintaining a pH range between **about** 4.0 and **about** 8.0, more preferably between about 5.5 and about 7.5 and more preferably at about 6.1.
>
> The stabilizing buffer should allow for the optimum activity of the lysin enzyme. The buffer may be a reducing reagent, such as dithiothreitol. The stabilizing agent may also be or include a metal chelating reagent, such as ethylenediaminetetraacetic acid disodium salt, or may also contain a citrate-phosphate buffer."

In fact, the above-mentioned "limitation is <u>exactly</u> a preferred embodiment. The words "may be" are used in this paragraph. The claim as it exists sets forth sufficient conditions for the operation of the invention. No undue experimentation is needed by one skilled in the art to use this invention based on the claim.

Additionally, one does not have to recite every reaction condition to have a valid claim under 35 U.S.C. 112, first paragraph.

The MPEP states:

2164,08(c) CRITICAL FEATURE NOT CLAIMED

A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

In the present invention, the words "may be" are used. The pH is not central to the functionality of the invention, only as to its preferred functional conditions.

Additionally, MPEP 2164.04 states in part:

2164.04 BURDEN ON THE EXAMINER UNDER THE ENABLEMENT REQUIREMENT

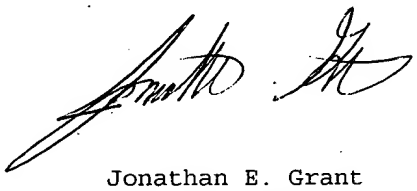
In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In light of **2164.04**, the Office Action has not provided any evidence or specific findings of the fact that would support a conclusion that the instant claims are not enabled. The rejection fails to set forth any factors, reasons, or evidence that lead the Office to conclude that the specification fails to make and use the claimed invention without undue experimentation. It is incumbent upon the Patent Office, whenever a rejection on this basis is made,

to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi and Horton*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971). Therefore, it is respectfully submitted that the rejection fails to set forth any substantive basis required to make a *prima facie* case of nonenablement under 112, first paragraph. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Please call the undersigned at (301) 603-9071 if you have any questions. Thank you.

Respectfully submitted,



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